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MAR - 7 2011

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Given Imaging Ltd. Hermon Building New Industrial Park PO Box 258 Yokneam 20692 Israel Tel.: 011-972-4-9097936 Fax: 011-972-4-9938060
Contact Person:	Tim Thomas Vice President, Regulatory Affairs and Quality Assurance Email: tim.thomas@givenimaging.com
Phone Number:	770-662-0870 ext. 1006
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Establishment Registration Number:	9710107
Date Prepared:	May 3, 2010
Device Trade Name(s):	Given PillCam® Platform with PillCam® SB Capsules
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300 Class: II Panel: Gastroenterology NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule
Predicate Device(s):	Given® Diagnostic System with PillCam® SB2 Capsule (K090557)
General Device Description:	The Given PillCam® Platform is comprised of three main subsystems; (1) the ingestible PillCam capsule, (2) the RAPID® software, and (3) the Given® Workstation and Hardware.

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1. Ingestible PillCam Capsule

The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the DataRecorder located outside the body.

2 RAPID Software

The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the DataRecorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms.

3 Given Workstation and Hardware

The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The DataRecorder is an external receiving/recording unit that receives acquired images from the capsule. The SensorArray receives data from the PillCam capsule and transfers the data to the DataRecorder. The RAPID *Real Time* is a handheld device that allows for real-time viewing of acquired images through the GI tract. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.

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Intended Use:	SB Indications for Use:

The PillCam Platform with a PillCam SB capsules is intended for visualization of the small bowel mucosa.

- The PillCam Platform with PillCam SB capsules may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- The PillCam Platform with PillCam SB capsules may be used in the visualization of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- The PillCam Platform with PillCam SB capsules may be used in the visualization of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.

The PillCam Platform with PillCam SB capsules may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.

Technological Characteristics:	The technology characteristics are exactly the same as the predicate devices.
Performance Data:	The devices meet the guidance entitled "*Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA* dated November 28, 2001. Clinical data has been summarized to show safety and effectiveness for the proposed indication for use.
Conclusion:	Based on the technological characteristics and clinical performance of the devices, Given Imaging Ltd. believes that the Given PillCam® Platform with PillCam® SB Capsules and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim Thomas
Vice President, Regulatory Affairs & Quality Assurance
Given Imaging Ltd.
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ISRAEL

MAR - 7 2011

Re: K101250
Trade/Device Name: Given PillCam® Platform with PillCam® SB Capsules
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastro-intestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: February 26, 2011
Received: March 1, 2011

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

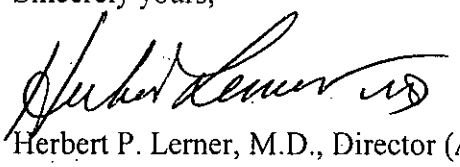
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K101250

Device Name: Given PillCam® Platform with PillCam® SB Capsules

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101250